

AMENDMENT NO. \_\_\_\_\_

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**Signature of Sponsor**

**FILED**

Date \_\_\_\_\_

Time \_\_\_\_\_

Clerk \_\_\_\_\_

Comm. Amdt. \_\_\_\_\_

**AMEND Senate Bill No. 1348**

**House Bill No. 1113**

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 39, Chapter 17, Part 4, is amended by adding a new section thereto, as follows:

Section 39-17-431. (a) Except as hereinafter provided, any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine may be dispensed only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription drugs.

(b) Any product containing ephedrine, as described in subdivision (b)(1-4) below, shall be exempt from subsection (a) if it may lawfully be sold over the counter without a prescription under the federal Food, Drug, and Cosmetic Act; is labeled and marketed in a manner consistent with the pertinent OTC Tentative Final or Final Monograph; and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse:

(1) Solid oral dosage forms (including soft gelatin caplets) that combine active ingredients in the following ranges for each dosage unit:

(i) Theophylline (100 - 130 mg), Ephedrine (12.5 - 24 mg);

(ii) Theophylline (60 - 100 mg), Ephedrine (12.5 - 24 mg), Guaifenesin (200 - 400 mg);

(iii) Ephedrine (12.5 - 25 mg), Guaifenesin (200 - 400 mg);

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(iv) Phenobarbital (not greater than 8 mg) in combination with ingredients of subdivision (1) or (2) above.

(2) Liquid oral dosage forms that combine active ingredients in the following ranges for each (5 ml) dose:

(i) Theophylline (not greater than 45 mg), Ephedrine (not greater than 36 mg), Guaifenesin (not greater than 100 mg), Phenobarbital (not greater than 12 mg);

(ii) Phenylephrine (not greater than 5 mg), Ephedrine (not greater than 5 mg), chlorpheniramine (not greater than 2 mg), dextromethorphan (not greater than 10 mg), ammonium C1 (not greater than 40 mg), ipecac fluid extract (not greater than 0.005 ml).

(3) Anorectal preparations containing less than five percent (5%) ephedrine.

(4) Any liquid compound mixture, or preparation containing one-half percent (0.5%) or less of ephedrine.

(d) The marketing, advertising, or labeling of any product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine, for the indication of stimulation, mental alertness, weight loss, appetite control, or energy, is prohibited.

In determining compliance with this requirement the following factors may be considered:

(1) The packaging of the drug product;

(2) The name and labeling of the product;

(3) The manner of distribution, advertising, and promotion of the product;

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(4) Verbal representations made concerning the products;

(5) The duration, scope, and significance of abuse or misuse of the particular product.

(e) Violation of any provision of this section is a Class A misdemeanor punishable by fine only.

SECTION 2. This act shall take effect July 1, 1995, the public welfare requiring it.